REMARKS

I. INTRODUCTION

Claims 1, 3-5 and 7-10 are currently pending in the present application. Claims 1, 3-5 and 7-10 have been rejected under 35 U.S.C. § 103(a). In accordance with the following remarks, Applicant respectfully submits that the pending claims are in condition for allowance.

II. REJECTIONS UNDER 35 U.S.C. §103 (a)

Claims 1, 3, 5, 7 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,466,888 ("Verkaart") in view of U.S. Patent No. 5,472,605 ("Zuk, Jr.") and U.S. Patent No. 5,607,830 ("Biesel *et al.*"). In addition, claims 4, 8 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Verkaart in view of Zuk, Jr. and Biesel *et al.* as applied to claim 1, 3, 5, 7 and 9 above, and further in view of U.S. Patent No. 5,643,193 ("Papillon *et al.*"). Applicant respectfully submits that these rejections should be withdrawn for at least the following reasons.

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103(a), not only must the prior art teach or suggest each element of the claim, but the prior art must also suggest combining the elements in the manner contemplated by the claim. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F. 2d 931, 934 (Fed. Cir. 1990), *cert. denied* 111 S.Ct.

296 (1990); *In re Bond*, 910 F. 2d 831, 834 (Fed. Cir. 1990). The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *See* M.P.E.P. §2142. To establish a *prima facie* case of obviousness, the Examiner must show, *inter alia*, that there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references and that, when so modified or combined, the prior art teaches or suggests all of the claim limitations. *See* M.P.E.P. §2143. Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

Verkaart is directed to a suction liquid collection assembly and flexible collecting bag therefor. According to Verkaart, the collection assembly includes "a disposable, flexible liner ... positioned within a vacuum chamber ... [wherein] the vacuum chamber is readily sealed despite the inlet ports to the disposable bag." Verkaart, col. 2, lines 12-17. Verkaart discloses a blood collection bag which is positioned between two shells, wherein the bag includes a particulate material filter which divides the bag into two chambers. *See* Verkaart, col. 2, lines 55-57; col. 3, lines 59-61; figs. 1, 4-5. Verkaart further notes "that the particulate material filter 70 divides the bag into defoaming and reservoir chambers and is not located in the air path between the inlet 80 and outlet 86. In past systems where a filter is positioned across the inlet, the drawing of an air/liquid mixture through the filter has resulted in excessive foaming. With this particular arrangement the liquid is separated from the air in the region above the filter, and the liquid then passes down through the filter by gravity feed." Verkaart, col. 5, lines 19-28. That is, according to Verkaart, the

liquid and the air are separated, and only the liquid passes through the particulate material filter.

Zuk, Jr. is directed to a filtration device useable for removal of leukocytes and other blood components. Zuk, Jr. discloses a device including "a first chamber which is in fluid flow relationship with a second chamber. Filtration elements separate the first chamber from the second chamber so that liquid flowing from the first chamber is filtered thereby prior to entry into the second chamber. A passage leads from the second chamber into the first chamber and a hydrophobic filter may be used to prevent liquid from the first chamber from flowing through the passage into the second chamber while allowing air to flow therethrough. An outlet is located in the second chamber, preferably at the bottom thereof." Zuk, Jr., abstract. Thus, according to the disclosure of Zuk, Jr., although a hydrophobic filter may be used to prevent the passage of liquid through the filtration elements, it will not prevent the passage of air therethrough.

Biesel *et al.* is directed to a method for the continuous conditioning of a cell suspension. According to the method and apparatus disclosed in Biesel *et al.*, "the cell suspension is centrifuged and the separated components of the cell suspension are separately removed." Biesel *et al.*, col. 1, lines 11-13. As previously described in the Response to the Office Action mailed on March 28, 2003, the current specification has been amended to incorporate Biesel *et al.* (U.S. Patent No. 5,607,830) by reference, which is the U.S. equivalent of the previously cited German Patent No. 42 26 974.

Papillon *et al.* is directed to an apparatus for the collection, washing and reinfusion of shed blood. According to Papillon *et al.*, the number of components and steps needed to collect, wash and reinfuse blood is reduced in the apparatus of Papillon *et al.* "by modifying the centrifuge bowl and locating it between the surgical site and the vacuum source." Papillon *et al.*, col. 2, lines 63-64. The apparatus of Papillon *et al.* includes a tube 10 for collecting blood from a surgical site, connected via a coupling 11 to an aspiration line 12 which "connects to the inlet port 22 of a centrifuge bowl 25, which is itself part of a centrifuge apparatus 24 that comprises the bowl 25 and means for rotating the bowl which are not shown." Papillon *et al.*, col. 4, lines 7-10. According to Papillon *et al.*, a vacuum source 34 applies negative pressure thereby drawing blood from the surgical site into tube 10, coupling 11, and aspiration line 12, where the blood then "enters input port 22 and passes through the filter 42 into the separation chamber 48 of centrifuge bowl 25, which is rotating at about 2000 to 3000 rpm." Papillon *et al.*, col. 4, lines 61-63.

Although the Examiner has alleged that "it would have been obvious to one of ordinary skill in the art to modify Verkaart's device to include a filter capable of removing toxins such as leukocytes given Zuk[, Jr.]'s teaching that this is old and well known in the art[, and] ... to use a centrifuge such as that disclosed by Biesel et al. in place of the centrifuge in Verkaart's device given the references [sic] teaching that this centrifuge eliminates the need to remove or drain the centrifuge bowl as with the prior art devices ... " (Office Action mailed 2/12/04, page 3, paragraph 6), Applicant respectfully disagrees in regard to the pending claims. It is respectfully submitted that a *prima facie* case of obviousness has not

been established by the cited patents because the modification of the apparatus of the primary reference of Verkaart (in view of Zuk, Jr. and Biesel *et al.*) to include the filter device for leukocyte depletion disclosed in Zuk, Jr., would change the principle of operation of the assembly and device disclosed in the primary reference of Verkaart. *See In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959) (court reversed rejection of claims holding that the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principles under which the [primary reference's] construction was designed to operate"). That is, Verkaart discloses an assembly for collecting liquids by suction, wherein the particulate material filter "is not located in the air path between the inlet 80 and outlet 86." Verkaart, col. 5, lines 21-22. According to the assembly of Verkaart, "the liquid is separated from the air in the region above the filter, and the liquid then passes down through the filter by gravity feed," whereas "[i]n past systems where a filter is positioned across the inlet, the drawing of an air/liquid mixture through the filter has resulted in excessive foaming." Verkaart, col. 5, lines 22-28. Verkaart does not teach nor suggest a device in which a filter is located in the air path between an inlet and an outlet, as is the device of Zuk, Jr., and there is no teaching, suggestion, nor motivation to replace the filter arrangement of Verkaart with one in which the filter is located in the air path between an inlet and an outlet. Furthermore, to modify the assembly of Verkaart to include such a filter arrangement would require a substantial redesign of the assembly while rendering it unsatisfactory for its intended purpose as it would no longer "minimize[] the amount of foaming of the blood and ... the possibility that any foam produced be taken off through the vacuum outlet." Verkaart, col. 2, lines 17-20.

Applicant also respectfully submits that the Examiner's conclusion of obviousness is improperly based on hindsight reasoning. *See In re McLaughlin*, 443 F.2d 1392, 170 U.S.P.Q. 209 (C.C.P.A. 1971). That is, the Examiner has not pointed to any prior art teaching nor suggestion regarding the desirability of the specifically claimed combination of components and method steps which comprise the autotransfusion set and method of autologous blood transfusion, respectively, of the present invention. Specifically, there is no teaching, suggestion nor motivation to replace the particulate material filter of Verkaart, which is used "to remove bone fragments and the like from the blood" (Verkaart, col. 1, lines 46-47), with a "filter means for eliminating at least one of leukocytes and tumor cells." The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Although the Applicant's own disclosure teaches the desirability of such specifically claimed combinations, the Examiner may not properly rely upon "knowledge gleaned only from Applicant's disclosure" in constructing the obviousness rejection. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 U.S.P.Q. 209, 212 (C.C.P.A. 1971).

For at least the preceding reasons, Applicant respectfully submits that the rejection of pending claims 1, 3-5 and 7-10 under 35 U.S.C. § 103(a) has been overcome and should therefore be withdrawn.

III. CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,
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